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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/828,143	03/24/1997	HOUN SIMON HSIA	24400-101	4526

7590 02/27/2004

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EXAMINER	
MARX, IRENE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/828,143	HSIA, HOUN SIMON	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-42* is/are pending in the application.

4a) Of the above claim(s) *9-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment filed 1/26/04 is acknowledged.

Claims 36-42 are being examined on the merits. Claims 9-11 remain withdrawn from consideration as directed to a non-elected invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pena Mecho *et al.* (U.S. Patent No. 3,243,299) taken with Cajigas, of record.

The claims are directed to a composition comprising dried viable *Lactobacillus,* dead Brewer's or Baker's yeast and soy, whey or animal protein concentrate in a sealed container.

The cited reference discloses a composition comprising dried viable *Lactobacillus,* dead Brewer's or Baker's yeast and soy protein concentrate which appears to be identical to the presently claimed composition (See, e.g., col. 5 and 6) since the material contains about 11.3 % yeast in Formula II concentrate. The reference recognizes that the added yeast aids in the growth of *Lactobacillus* and additionally that the composition has health benefits as a nutritional supplement.

The reference differs from the claimed invention in that it is silent as to placement in a sealed container. However the formulation is clearly suitable for storage in a sealed container, as

suggested by the teachings of Cajigas (See, e.g., col. 8, lines 11-15). For storage purposes, the bulk composition of Pena Mecho *et al.* may be stored as is in a sealed container or may be divided into smaller portions for the sake of convenience and for distribution by placing in sealed containers such as sacks, jars or barrels, for example.

The referenced composition also may differ from the claimed invention in that the amount of *Lactobacillus* appears to be less than the amount required in claims 38 and 39 and the amount of protein concentrate is less than that required in claim 42. However, Cajigas recommends that the amount of *Lactobacillus* be up to 5% (Col. 3, lines 41-47). In addition, it would have been within the ordinary skill in this art to adjust the amounts of *Lactobacillus,* yeast and protein to maximize the benefits of the composition depending on the specifically targeted subject, with respect to therapeutic, dietetic or food requirements.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition of Pena Mecho *et al.* by placing it in one or more sealed containers as taught by Cajigas, and further by adjusting the respective concentrations of *Lactobacillus,* yeast and protein according to the specific needs of the particular subject to be fed or treated, for the expected benefit of maximizing the therapeutic, health and nutritional effects of the *Lactobacillus,* yeast and protein concentrate composition.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant appears to argue that the claimed composition is drier than the composition shown in the reference. However, the degree or extent of dryness is not part of the claimed invention. In other words, there is no indication that the moisture is 0. That the composition of Pena Mecho *et al.* contains a low level of moisture is not seen as a distinguishing feature over the claimed compositions, since it pertains to a property that is not claimed. In fact, no reference is found in the instant disclosure regarding the extent of drying of the composition of interest. The independent claim invention does not even specify the amount of dried, viable bacteria comprised by the invention or the amount of protein therein. With respect to the "kind" of

protein concentrate disclosed by applicant, the claims are directed to "a protein concentrate selected from the group consisting of whey protein, soy protein, and animal protein concentrates." No mention is made in the claim designated invention of a particular kind of protein required. In response to applicant's arguments with respect to the amount of protein in claims 41-42 and the amount of bacteria in claims 38-39, respectively, applicant has not demonstrated that the amounts listed impart any unusual or unexpected properties to a nutritional composition, particularly in the broad ranges recited. One of ordinary skill in this art would recognize that the adjustment of the concentration of the ingredients would depend on the particular population targetted for administration of the nutritional composition and the specific needs of this population. Moreover, the composition of col. 6, lines 50 et seq. contains 68.75% soya, which appears to be within experimental error of the lower limit of the range of "about 75%." Regarding the concentration of bacteria, applicant's argument is not understood, since it is only the lactic acid element of "Pronit" that is relevant to the invention as claimed.

With respect to the purpose of the sealed container, there is no indication in the claimed invention that the container is vacuum sealed, for example, or that it is sealed in the absence of moisture and/or to exclude moisture. The definition of sealed in The American Heritage® Dictionary of the English Language, Fourth Edition. 2000, is:

a. To close with or as if with a seal.

b. To close hermetically.

c. To make fast or fill up, as with plaster or cement.

d. To apply a waterproof coating to: *seal a blacktop driveway.*

e. To affix a seal to in order to prove authenticity or attest to accuracy, legal weight, quality, or another standard.

f. An airtight closure.

g. A closure, as on a package, used to prove that the contents have not been tampered with.

Contrary to applicant's allegations, one having ordinary skill in the art at the time the claimed invention was made would reasonably have expected any and all nutritional compositions to be commercially provided in a sealed container at least to protect their integrity.

Therefore these arguments fail to persuade and the rejection is deemed proper and it is adhered to.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651